

## **REMARKS**

### **Specification**

In the specification, the paragraph bridging pages 12 and 13 has been amended to separate the descriptions for Figures 3B and 4 into separate paragraphs.

The Examiner objected to the drawings for allegedly failing to comply with 37 CFR 1.84(p)(5). In response, the two paragraphs at page 15, line 31 through page 16, line 6; and the paragraph and heading at page 103, lines 16-29 have been amended to add the Figure titles, *i.e.*, Figures 18A and 18B, to the description as suggested by the Examiner.

No new matter has been added.

### **Information Disclosure Statement**

Applicants have submitted a Supplemental Information Disclosure Statement containing copies of references, now labeled B01 to B08 and C01 to C26 that were cited in the Information Disclosure Statement dated October 28, 2005, but were not considered by the Examiner. In addition, the Supplemental Information Disclosure Statement also includes copies of references A01-A04 and B09. Applicants respectfully request that the references be made of record in the application.

### **Claims**

Claims 100-104, 109 and 111-124 were pending in the present application. Applicants have amended claims 100, 101, and 118; and canceled claims 102 and 114-116 without prejudice to Applicants' right to pursue the subject matter of the canceled claims in a related application. Applicants have also added new claims 125 to 140 to more particularly point out and distinctly claim the invention. Upon entry of this amendment, claims 100-101, 103-104, 109, 111-113, and 117-140 will be pending.

Claim 100 has been amended to recite that the hapten has the structure of nicotine-1'-N-oxide, trans-3'-hydroxycotinine or nicotine glucoronide can be found, for example, at page 34, lines 24-27 in combination with Figure 19. Support for the recitation that Y is S, O, or NH can be found, for example, at page 36, lines 14-15. Claim 101 has been amended to recite that n is from 3 to 20 for purposes of clarity. Support for the amendment to claim 101

can be found, for example, at page 36, lines 12-14. Claim 118 has been amended to correct a typographical error.

New claims 125-140 relate to a hapten-carrier conjugate comprising at least one hapten derived from nicotine, wherein the hapten is nicotine; and at least one carrier containing a T cell epitope wherein the hapten and carrier are linked as specified in claim 125. Support for new claim 125-140 can be found, for example, in the table as set forth below. No new matter has been added.

<u>Claim No.</u>	<u>Support</u>
125	Page 34, line 24 through page 37, line 8
126	Page 36, lines 13-14
127	Page 27, line 30 through page 28, line 18
128	Page 46, lines 1-2; page 53, lines 7-8
129	Page 27, line 34 through page 28, line 14
130	Page 27, line 34 through page 28, line 14
131	Page 54, lines 20-21
132	Page 23, lines 6-9
133	Page 54, lines 7-8
134	Page 54, lines 1-3
135	Page 54, lines 1-3
136	Page 55, lines 15-17
137	Page 57, lines 4-16
138	Page 56, lines 4-9 in combination with page 56, line 30 through page 57, line 5
139	Page 27, line 34 through page 28, line 14 in combination with page 54, lines 20-21
140	Page 27, line 34 through page 28, line 14 in combination with page 54, lines 20-21; and page 23, lines 7-9

# I. Priority

The Examiner contends that Applicants are not entitled to the priority benefit of U.S. application Serial No. 08/414,971 and U.S. application Serial No. 08/563,673, now U.S.

Patent No. 5,760,184 for one or more of the pending claims. Applicants respectfully disagree. Applicants submit that new claims 126-128, 130-134, and 136-140 are supported, at a minimum, by the prior-filed application Serial No. 08/414,971, filed March 30, 1995; and that new claims 125, 129, and 135 are supported, at a minimum, by the prior-filed application Serial No. 08/563,673, filed November 28, 1995.

Support for claims new claims 126-128, 130-134, and 136-140 can be found in application Serial No. 08/414,971, for example, in the table as set forth below.

<u>Claim No.</u>	<u>Support in U.S. application Serial No. 08/414,971</u>
126	Page 14, line 31 through page 15, line 4; page 20, line 4 through page 21, line 28; and Figure 6 in combination with Figure 2A and page 8, lines 1-3
127	Page 15, line 35 through page 16, line 13
128	Page 14, lines 8-12
130	Page 15, line 35 through page 16, line 1; and page 18, lines 2-8
131	Page 28, lines 20-25
132	Page 12, lines 23-25 and page 28, line 8-17 and 30-33
133	Page 28, lines 8-17
134	Page 28, lines 11-14
136	Page 28, lines 26-30
137	Page 29, lines 25-30
138	Page 29, lines 25-30 and page 30, lines 9-17
139	Page 28, lines 20-25
140	Page 12, lines 23-25 and page 28, line 8-17 and 30-33

Support for claims new claims 125-140 can be found in U.S. application Serial No. 08/563,673, for example, in the table as set forth below.

<u>Claim No.</u>	<u>Support in U.S application Serial No. 08/563,673</u>
125	Page 16, lines 14-21; page 21, line 32 through page 22, line 3; page 22, line 5 through page 23, line 34; Figure 2A in combination with page 7, lines 10-12;
126	Page 23, lines 8-10
127	Page 17, lines 9-28; page 19, lines 4-13
128	Page 15, lines 24-28
129	Page 17, lines 9-28
130	Page 17, lines 9-28
131	Page 33, lines 13-18
132	Page 32, line 25 through page 33, line 9; page 33, lines 22-25
133	Page 32, line 31 through page 33, line 4
134	Page 32, line 31 through page 33, line 1
135	Page 32, line 31 through page 33, line 1
136	Page 33, lines 18-25; page 33, line 32 through page 33, line 2
137	Page 34, lines 26-28
138	Page 34, lines 21-22; page 35 , lines 7-14
139	Page 33, lines 13-18
140	Page 32, line 25 through page 33, line 9; page 33, lines 22-25

Accordingly, pending claims 126-128, 130-134, and 136-140 are, at a minimum, entitled to the priority of U.S. application Serial No. 08/414,971, filed March 30, 1995; and claims 125, 129, and 135 are, at a minimum, entitled to the priority of U.S. application Serial No. 08/563,673, filed November 28, 1995.

## **II. The Objection To Claims 114-116 Should Be Withdrawn.**

Claims 114-116 are rejected because the claims reference the structures in Figure 19.

Without conceding to the propriety of the rejection, and in order to expedite prosecution of the present application, Applicants have canceled claims 114-116, thereby

rendering the grounds for the rejection moot. Withdrawal of the rejection is respectfully requested.

### **III. The Claims Are Not Anticipated By U.S. Patent No. 5,164,504 to Walling *et al.***

Claims 100-103, 111 and 114-115 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent No. 5,164,504 to Walling *et al.* ("Walling"). The Examiner alleges that Walling discloses certain hapten-carrier conjugates wherein the hapten is cotinine. For the reasons below, the rejection cannot stand and should be withdrawn.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Without conceding to the propriety of the rejection, and in order to expedite prosecution, Applicants have amended claim 100 to specify that the hapten is nicotine-1'-N-oxide, trans-3'-hydroxycotinine or nicotine glucuronide. Walling fails to teach a hapten-carrier conjugate wherein the hapten is nicotine-1'-N-oxide, trans-3'-hydroxycotinine or nicotine glucuronide. Accordingly, Applicants submit that the rejection is moot.

Further, Applicants submit that that the rejection under 35 U.S.C. § 102(b) should not be applied to new claims 125-140 because Walling fails to teach hapten-carrier conjugates wherein the hapten is nicotine. Accordingly, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 102(b) are respectfully requested.

### **IV. The Claims Are Not Anticipated By U.S. Patent No. 5,843,680 to Manian *et al.***

Claims 100, 103, and 114 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent No. 5,843,680 to Manian *et al.* ("Manian"). The Examiner alleges that Manian teaches nicotine hapten-carrier conjugates wherein the carriers are polypeptides. Furthermore, the Examiner contends that Manian teaches that the carrier is directly linked to the hapten. For the reasons below, Applicants respectfully disagree.

Manian describes analytes of haptens that are immunologically active when conjugated to a carrier, which in some embodiments can be a polypeptide. Manian describes nicotine as an example of such a hapten. However, Manian fails to teach or suggest how the

hapten is bound to the polypeptide. In contrast to the Examiner's contention, the reference is silent on how the hapten is conjugated to a carrier, *i.e.*, Manian fails to describe that the carrier is directly linked to the hapten. Manian, for instance, fails to teach or suggest the linkers recited in claim 100.

Manian also fails to teach or suggest a carrier containing a T cell epitope as specified by the pending claims. The specification of the present application teaches that the hapten-carrier conjugate, *inter alia*, is capable of stimulating T cells which leads to T-cell proliferation and a characteristic release of mediators which activate relevant B cells and stimulate specific production (see, *e.g.*, page 25, lines 29-35 of the present specification).

Furthermore, Manian fails to teach a hapten-carrier conjugate wherein the hapten is nicotine-1'-N-oxide, trans-3'-hydroxycotinine or nicotine glucuronide as specified in claim 100.

Thus, Manian does not teach each and every element of claims 100, 103, 114, and 125, and therefore, does not anticipate the claimed invention.

The rejection under 35 U.S.C. § 102(b) should not be applied to new claims 125-140 because Manian fails to describe how the hapten is bound to a polypeptide, nor does it teach or suggest a carrier containing a T cell epitope as specified in claims 125-140.

In view of the foregoing, the rejection of claims 100, 103, and 114 under 35 § U.S.C. 102(b) as allegedly anticipated by Manian cannot stand and should be withdrawn.

**V. The Double Patenting Rejection Of Claims 100-104, 109 and 111-124 Over Claims 1-2, 4-5, 8-12, and 17-18 of U.S. Patent No. 5,876,727 Should Be Held In Abeyance.**

Claims 100-104, 109, and 111-124 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-5, 8-12, and 17-18 of U.S. Patent No. 5,876,727. Applicants respectfully request that the rejection be held in abeyance until such time as the Examiner indicates there is allowable subject matter, at which time the matter will be revisited in light of the allowable subject matter.

**VI. The Provisional Double Patenting Rejections Should Be Held In Abeyance.**

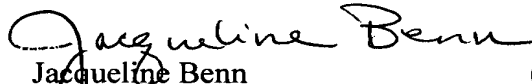
Claims 100-104, 109 and 111-124 are provisionally rejected on the non-statutory ground of obviousness-type double patenting over claims 43-45, 47-50, 52-54, 56-65, and 74-82 of copending Application Nos. 11/066,718; 11/472,215; 11/472,216; 11/472,217; 11/472,218; 11/472,219; 11/472,220; 11/472,222; and 11/472,223. The Examiner contends that although the claims are not identical to each other, they are not patentably distinct from each other. Applicants respectfully request that the rejection be held in abeyance until such time as the Examiner indicates there is allowable subject matter, at which time the matter will be revisited in light of the allowable subject matter.

**CONCLUSION**

Applicants respectfully request that the Examiner consider the amendments and the remarks made herein, and that the Examiner enter them into the record for the present application. Withdrawal of all rejections, and an allowance is earnestly sought. The Examiner is invited to contact the undersigned attorney if a telephone call could help resolve any remaining items.

Respectfully submitted,

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